

Group II consists of Claims 2-4, 6-8, 12-22 and 32-37, drawn to a microorganism that comprises a vector, first and second control sequences, a first repressor, a second repressor, a gene that encodes a desired product, and is attenuated.

Group III consists of Claims 9-11, drawn to a microorganism that comprises a balance lethal host vector system, a vector, a desired gene product, a first and second control sequences, and first and second origins of replication.

Group IV consists of Claims 23-31, drawn to a method of making a desired gene product.

Group V consists of Claim 38, drawn to a method of delivering a desired gene product to a vertebrate.

Applicants hereby elect Group II for further examination in the instant application. Applicants cancel Claims 1, 9-11, 23-31, and 38 from further consideration in the present application without prejudice to Applicants' rights to pursue the subject matter of these canceled claims in other patent applications.

ELECTION OF SPECIES

The Examiner requires that Applicants elect a single species for examination in the instant application. Upon allowance of a generic claim, Applicants shall be entitled to consideration of claims to additional species as provided under 37 C.F.R. 1.141.

With respect to the mutation to attenuate, Applicants hereby elect phoPQ.

With respect to the repressor sequence, Applicants hereby elect C2.

With respect to the control sequence, Applicants hereby provisionally elect P22P_T with traverse. The claimed invention calls for an activatable control sequence and a first control sequence. Support could be found, for example, on page 18, lines 12-15, page 19, lines 30-35, and Figure 1. As described in the specification, the Regulated Antigen Delivery System ("RADS") comprises a runaway vector ("RAV") and a repressor operably linked to an activatable control sequence. An inducer, such as arabinose, interacts with the activatable control sequence to activate expression of the repressor. The repressor, in turn, interacts with the first control sequence to prevent utilization of the second origin of replication ("ori") on the RAV. Thus, in the presence of an inducer, the microorganism cannot make high copies of the RAV. In the

absence of an inducer, on the other hand, the repressor is not expressed, thereby allowing the microorganism to switch to runaway expression. Accordingly, Applicants respectfully request that the Examiner allow Applicants to elect $\text{araCP}_{\text{BAD}}$ as the activatable control sequence and P22P_r as the first control sequence, rather than one control sequence from the Examiner's list. A RADS with only one control sequence would result in a molecular delivery system unintended by the Applicants.

With respect to the ori , Applicants hereby provisionally elect pUC with traverse. The RADS of the claimed invention comprises a RAV that has at least two different ori 's. Different ori 's allow the microorganism to switch from low copy to high copy replication and vice versa. (Specification on page 8, lines 12-15, Example 2 on page 50, 11-23, and Figure 1). For example, DNA polymerase III initiates replication at the first ori to allow for low copies of the RAV. In the absence of a repressor, DNA polymerase I initiates replication at the second ori to allow for high copies of the RAV. Thus, in the absence of a repressor, the RADS exposes a large dose of the vector-encoded foreign gene product to the vertebrate's lymphoid tissue, thereby efficiently eliciting an immune response. Applicants, therefore, respectfully, request that the Examiner allow Applicants to elect both pSC ori and pUC ori .

In summary, Applicants respectfully request that the Examiner allow Applicants to elect a single species with the following elements:

Mutation for attenuation: phoPQ

Repressor: C2

Control sequences: $\text{araCP}_{\text{BAD}}$ and P22P_r

Origins of replication: pSC and pUC

The Examiner has required that Applicants identify the claims that are readable on the elected species. Applicants assert that Claims 2-4, 5, 6-8, 12-22 and 32-37 are readable on the species elected above.

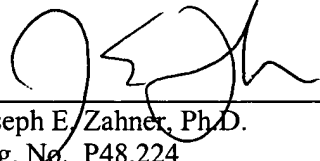
CONCLUSION

Applicants believe that they have complied with the Examiner's restriction requirement. Applicants respectfully request entry of the foregoing amendment and remarks into the file of the

• Application Serial No. 09/560,539

above-identified application. After the above election, Claims 2-4, 5, 6-8, 12-22 and 32-37 are now pending in the instant application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. Zahner', is written over a horizontal line.

Joseph E. Zahner, Ph.D.
Reg. No. P48,224
Howell & Haferkamp, L.C.
7733 Forsyth Boulevard, Suite 1400
St. Louis, Missouri 63105
(314) 727-5188